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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,381

10/28/2003

Albert K. Chin

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EXAMINER

SMITH, PHILIP ROBERT

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

10/31/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/696,381	Applicant(s) CHIN, ALBERT K.	
	Examiner PHILIP R. SMITH	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4,7,11,12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4,7 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

[01] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

[02] Claim 1,4,7,14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Horzewski (5,318,588) in view of Gibson (702,789) and in further view of Vandegrift (2,201,749).

[03] With regard to claim 1:

[03a] Horzewski discloses an apparatus for performing a surgical procedure in tissue comprising:

- an inner cannula ("dilator 150" 12/49) having an elongated body and a tip ("bulbous region 127" 12/64) that is positioned at a distal end of the elongated body and that is configured to dissect tissue ("dilator 150 contains a guidewire channel 122" 12/49); and
- an outer expandable sheath ("side arm sheath 90" 11/67) disposed about the inner cannula and disposed to contact tissue and configured to expand in an outward direction against tissue in contact therewith ("accommodate positive radial expansion over a specific range of radial dimensions" 12/7-9) responsive to the tip of the inner cannula slidably passing longitudinally through the sheath in a proximal direction through the sheath for removal therefrom ("Withdrawal of the dilator [150], however, through the confines of the sheath, increases the profile of the delivery channel to the desired profile as bulbous region 127 is withdrawn through the shaft" 13/12-15).

[03b] Horzewski does not disclose:

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- That the outer expandable sheath comprises first and second shells.

[03c] Gibson discloses:

- an outer expandable sheath ("tube A" 1/28) configured to expand in an outward direction responsive to the tip of an element ("rod D" having "plunger D2" 2/65) slidably passing longitudinally through the sheath (2/71-89). Gibson further discloses that the outer expandable sheath comprises a first shell and a second shell ("segmental bars e'," 2/60-70) adjacently aligned along longitudinal edges thereof.
- At the time of the invention, it would have been obvious to a person of ordinary skill in the art that the outer expandable sheath having resiliently connected first and second shells disclosed by Gibson be substituted for the outer expandable sheath disclosed by Horzewski. It is obvious to substitute one known element for another to obtain predictable results. Radially expansive tubes are known in the art, as are radially expansive shells. A skilled artisan could have substituted one for the other, and the resulting substitution would have been predictable.

[03d] Horzewski in view of Gibson does not disclose:

- that the first and second shells are configured as substantially half cylindrical segments. Instead, Gibson discloses "segmental bars" which are adjacently aligned along the longitudinal edges thereof. Figure 3 shows five such "segmental bars".

[03e] Vandegrift discloses:

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- an expanding vein tube which is "split vertically throughout the greater portion of its length along diametrically opposed lines as at 2,2 which provide semi-circular legs 3 and 4" (1/51-54). The tube disclosed by Vandegrift accomplishes a similar function to that of Horzewski in view of Gibson: expansion of an outer shell in response to a "plunger" or "dilator" being passed through it.
- At the time of the invention, it would have been obvious to a person of ordinary skill in the art that an outer shell having two half cylindrical segments configured to expand in response to a dilator ("3 and 4" as disclosed by Vandegrift) be substituted for the outer shell having five "segmental bars" which are configured to expand in response to a dilator (as disclosed by Horzewski in view of Gibson). A skilled artisan would be motivated to do so in order to provide for simpler manufacturing of the device, and fewer longitudinal slits with which to potentially injure the patient.

[04] With regard to claim 4: Gibson further discloses and a resilient connector ("thin soft rubber sheath C," 2/81) attached between the first and second shells for resiliently urging the longitudinal edges of the shells together.

[05] With regard to claim 7: the resilient connector disclosed by Gibson resiliently urges a distal end of the first shell toward a distal end of the second shell (a point indicated by "a2" in the figures) to form an inner dimension at the distal end of the outer expandable sheath smaller than the outer dimension of the tip in the absence of an outwardly expansive force applied to the distal end of the outer expandable sheath in response to the tip passing through the distal ends of the shells.

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- [06] With regard to claim 14: Horzewski discloses an elongated handle ("side arm 46" see Figure 3C) eccentrically attached near a proximal end of the inner cannula.

Response to Arguments

- [07] Applicant's arguments filed 8/4/08 have been fully considered but they are not persuasive.
- [08] Applicant asserts that neither Horzewski nor Gibson discloses all the recited elements of claim 1. Claim 1 stands rejected for the reasons stated above as being unpatentable over Horzewski in view of Gibson and Vandegrift.

Conclusion

- [09] **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
- [10] A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.
- [11] Any inquiry concerning this communication or earlier communications from the examiner should be directed to PHILIP R. SMITH whose telephone number is (571)272-6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.

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- [12] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [13] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
- [14] /Philip R Smith/
- [15] Examiner, Art Unit 3739
- [16] /Linda C Dvorak/
- [17] Supervisory Patent Examiner, Art Unit 3739